

For Immediate Release

Biota Confirms Relenza Stockpiling in Germany

Melbourne, Australia—15 August 2005. Biota Holdings Limited (ASX:BTA) announced today that it has received written confirmation from its licensee, GlaxoSmithKline (GSK), that the German government has placed an order for 1.7 million packs of Relenza, as reported in *The Australian* on 11 August.

"This is an important development," said Biota CEO, Peter Molloy. "More Relenza has been sold in this single order than over the last five years combined." The order is even larger than the 1.4m units of Relenza sold in its launch year (1999/00) when the drug was supported with active promotion by GSK.

Biota receives a 7% royalty on sales of Relenza and in 2003/04 reported around \$0.5m in royalty revenue; similar levels are expected in the 2004/05 year. With the German order representing more than 7 times last year's worldwide Relenza sales, the impact on Biota's royalties could be substantial, but the royalties received in the current 2005/06 year will depend on the pricing of the order and timing of invoicing and delivery.

"In Germany, Relenza normally sells for around US\$20 (\$26) per pack, but we have not been informed yet about the pricing of this stockpiling order," said Mr Molloy. Biota has contacted the German subsidiary of GSK seeking further details.

The German order is the first large stockpiling order for Relenza anywhere in the world and Biota hopes it's the start of a revival in the drug's sales through further stockpiling orders.

"We hope other countries will follow suit, including Australia," said Mr Molloy.

The prospects of such a revival have been boosted following recent calls by scientists and health officials for active stockpiling of Relenza in addition to its competitor, Tamiflu (oseltamivir). These came after an article appeared in the prestigious medical journal, *The Lancet*¹, which stated that 'Although both (drugs) have similar efficacy, zanamivir (Relenza) has fewer adverse reactions and a favourable resistance profile'. The authors recommended that governments consider stockpiling Relenza as part of their pandemic planning.

The Wall Street Journal on 12 August² described the German decision as an 'endorsement' of Relenza, amid concerns that Roche may be unable to meet the demand for supply of Tamiflu in the event of a pandemic. The concerns have been exacerbated by Gilead's recent decision to terminate Roche's license to Tamiflu. According to one report³, the availability problems with Tamiflu alone should prompt governments to consider ordering Relenza.

"Biota has consistently stated that both drugs should be stockpiled in line with sound healthcare practice," said Mr Molloy. "In this case, because of the shortage of supply of one drug, the serious consequences of a pandemic, and the recognised value of Relenza, the argument for dual stockpiling is compelling."

Biota estimates that sales of flu antivirals for stockpiling over the next two years could amount to US\$3 billion (\$3.9 billion). Even a modest share of these orders would yield substantial Relenza sales and royalties.

“We hope that our licensee, GSK, will actively pursue this opportunity to grow Relenza sales,” said Mr Molloy. Over the last 12 months, according to market audits*, GSK spent less than US\$200,000 worldwide on Relenza promotion to doctors, compared more than US\$30 million in the drug’s launch year. Notably 94% of the promotion spend in the last 12 months was in Germany.

Biota is currently suing GSK for failing to promote and support Relenza after the drug’s launch and is seeking damages of up to \$430 million. However, the claim is provisional and may increase, especially if the market continues to grow at its current rate. The case is scheduled for mediation in November 2005.

About Biota

Biota is a world-leading antiviral drug discovery company with its headquarters in Melbourne, Australia. Biota was responsible for zanamivir, the first in class neuraminidase inhibitor, subsequently launched by GSK as Relenza™ in 1999 for the treatment of influenza. In partnership with Sankyo, Biota is developing second generation flu antivirals (LANI or Long Acting Neuraminidase Inhibitors). Biota is also developing potential therapies for the common cold, (Human Rhinovirus or HRV infection, RSV (Respiratory Syncytial Virus) infection, and liver disease caused by hepatitis C. In partnership with Thermo Electron, Biota also markets the FLU OIA® diagnostics range for the rapid detection of influenza.

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™ Relenza is a registered trademark of the GlaxoSmithKline group of companies

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* IMS (Intercontinental Medical Statistics) provide independent audit data on the sales of pharmaceutical products worldwide.

1. Tsang, KWT, En, P, Liam, CK, Shim, Y, and Lam WK, “H5N1 influenza pandemic: contingency plans”, *The Lancet* 2005; 366:533-534.
2. Zamiska, N, “Glaxo Drug Gets Endorsement as a Treatment for Bird Flu”, *The Wall Street Journal*, 12 August 2005.
3. Branswell, H, “Countries urged to consider second antiviral drug for pandemic arsenals”. Canada.com/health, 12 August 2005.